DETAILED ACTION

Election/Restrictions

Although the restriction requirement in the Office Action dated 01 November 2006 indicates via typographical error that Group I is Claims 1-15 and Group II is Claims 16-10, the groups of claims are actually Group I, Claims 1-13 and Group II, Claims 1419. Applicant's response dated 21 June 2007 acknowledges these actual groupings.

Applicant's election of Group I, Claims 1-13, in the reply filed on 21 June 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 14-19 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 21 June 2007.

Claim Objections

Claims 1-11 are objected to because of the following informalities:

Claim 1, line 12 appears to mean "than" instead of "then" as presently indicated. Claims 2-11 are objected to via their dependency.

Claim 8, line 4 appears to mean "insert" instead of "inert."

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkozi (US Patent No. 5,1381,774) in view of Swartz et al. (US Patent No. 6,346,210 B1) and Healy et al. (US Patent No. 5,951,935).

With respect to Claim 1, Sarkozi teaches making a customized insole liner (a method for manufacturing custom fit therapeutic footwear) (see Abstract) by providing a lining element 10 (providing a first insert) (see fig. 3 and col. 3, lines 22-27), forming openings 15, 16, 17 through layers 12, 14 where support is needed (forming an area of reduced thickness in the first insert corresponding to the at least one of the high pressure areas) (see col. 2, lines 26-30 and col. 3, line 64 through col. 4, line 6), providing a base pad 25 into the lining element 10 (providing a mass of a second insert material; partially filling the area of reduced thickness in the first insert with a mass of the second insert material to thereby provide a custom molded insert with accommodation) (see col. 4, lines 43-46). Since Sarkozi adjusts as the pads of the lining element based on the patient's foot (see col. 2, lines 26-30), the patient's foot is measured.

Sarkozi does not expressly teach imprinting a patient's foot to identify a patient's footprint and high pressure areas on the bottom of the foot, that the lining element 10 is multidensity and fabricated from a mold of the foot, and that the base pad 20 is a softer hardness than the first insert material.

Swartz teaches making a foot pad 50 with different densities by imprinting the foot against the foam (the lining element 10 is multidensity and fabricated from a mold of the foot; imprinting a patient's foot to identify a patient's footprint and high pressure areas on the bottom of the foot) (see abstract; fig. 3; and col. 6, lines 44-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Swartz's method to make adjustable Sarkozi's lining element 10 in order to absorb shock (see Swartz, col. 6, lines 44-50).

Healy teaches to provide a sock liner member 30 with elastomeric pads 32, 34 that are softer than the sock liner member 30 (the base pad 20 is a softer hardness than the first insert material) (see col. 2, lines 36-46 and col. 3, lines 8-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to Healy's softer elastomeric pads as the base pad 25 of Sarkozi in order to have excellent cushioning, shock absorption, and energy return (see Healy, col. 1, lines 25-34).

With respect to Claim 2, Sarkozi teaches to use the insole liner for shoes (inserting the custom fit inserts into a shoe) (see abstract).

With respect to Claim 3, Sarkozi teaches that the layers 13, 14 of the lining element 10 are $^1/_{64}$" - $^1/_4$" thick before forming an opening and thus removing a layer in that area (see col. 3, lines 40-41 and line 64 through col. 4, line 6), which would be a thickness reduction of ($^1/_{64}$")/($^1/_{64}$" + $^1/_4$") to ($^1/_4$")/($^1/_{64}$" + $^1/_4$") or 6-94%, which reads on the claimed reduction of 75%.

Alternatively, if it is held that Sarkozi does not appear to explicitly teach that thickness reduction is within the claimed range (e.g., about 75%), in this regard, Sarkozi teaches providing liner element 10 layer thickness sufficient to allow insertion and retention of the base pads (see col. 3, lines 40-45). As such, Sarkozi recognizes that the thickness of the liner element 10's layers is a result-effective variable. Since the thickness of the liner element 10's layers is a result-effective variable, one of ordinary skill in the art would have obviously been motivated to determine the optimum the thickness of the liner element 10's layers applied in the process of Sarkozi through routine experimentation based upon the need to insert and hold an appropriate base pad.

With respect to Claim 4, Sarkozi teaches that the layers 13, 14 of the lining element 10 (first insert material) are $^{1}/_{64}$" - $^{1}/_{4}$" thick before forming an opening and thus removing a layer in that area (see col. 3, lines 40-41 and col. 3, line 64 through col. 4, line 6), which would provide for a composite of $^{1}/_{32}$" - $^{1}/_{2}$" given the negligible size of layers 11 and 12 (see fig. 3), which reads on the claimed thickness of about $^{5}/_{8}$ inch. Sarkozi teaches that the stack of removable pads 25, 26 (second insert material) is $^{1}/_{64}$" - $^{1}/_{2}$" (see col. 4, lines 56-61), which reads on the claimed thickness of about $^{1}/_{16}$ inch.

With respect to Claim 5, Sarkozi teaches that the lining element 10 (first insert) is made of polyethylene (see col. 3, lines 22-45) and that the base pads (second insert material) are made of foam polyurethane (see col. 6, lines 19-32).

With respect to Claim 6, Sarkozi teaches forming openings 15, 16, 17 in the lining element through bottom layers 12, 14 (reduced thickness is formed by abrading a

selected portion of the first insert material with an abrasive) (see col. 3, line 64 through col. 4, line 2).

With respect to Claims 7 and 8, Sarkozi teaches that the openings have smaller surface area than the cavities filled by the base pad (adding a pad around the area of reduced thickness) (see col. 4, lines 2-6), that the pads 25, 27 may be made from the same material as the lining element 10 (first insert material) (see col. 6, lines 19-32), and that the stack of removable pads 25, 26 (a pad of said first insert material) is $^1/_{64}$" - $^1/_2$" (see col. 4, lines 56-61), which reads on the claimed thickness of about $^1/_8$ inch. To clarify, one of the pads 25, 27 may be considered one of the second insert and the pad around the area of reduced thickness. Furthermore, the other of the pads 25, 27 would be considered the other of the second insert and the pad around the area of reduced thickness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkozi (US Patent No. 5,1381,774) in view of Swartz et al. (US Patent No. 6,346,210 B1) and Healy et al. (US Patent No. 5,951,935) as applied to Claim 1-8 above and further in view of Scholl (US Patent No. 1,725,021).

With respect to Claim 10, Sarkozi teaches to use the insole liner for shoes (inserting the custom fit inserts into a shoe) (see abstract). Sarkozi does not expressly teach tracing an outline of the patient's foot on the imprint, sizing a shoe based on the outline of the patient's foot and selecting a manufactured shoe to fit the patient's foot.

Scholl teaches using a pencil to trace the outlines of the foot (tracing an outline of the patient's foot on the imprint) (see page 2 of text, lines 78-94).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to trace as taught by Scholl on the imprint of Sarkozi in order to depict, as nearly as possible, the outline of the foot for which the shoe is intended in order that the last may be made to substantially conform to the configuration of the foot for a shoemaker (sizing a shoe based on the outline of the patient's foot and selecting a manufactured shoe to fit the patient's foot) (see page 1 of text, lines 19-21 and 58-64).

Claims 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkozi (US Patent No. 5,1381,774) in view of Swartz et al. (US Patent No. 6,346,210 B1) and Healy et al. (US Patent No. 5,951,935) as applied to Claim 1-8 above and further in view of Brown (US Patent No. 3,995,002).

With respect to Claim 9, Sarkozi teaches making an insert as previously described. Sarkozi does not appear to expressly teach the steps of forming a mold of a lower portion of the patient's foot and forming a cast of the lower portion of the patient's foot from the mold.

Brown teaches to product a negative mold of a foot to produce a positive form (forming a mold of a lower portion of the patient's foot and forming a cast of the lower portion of the patient's foot from the mold) (see Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Brown's method of forming a negative and then positive mold with Sarkozi's method of making an insert in order to allow the insert to be made in accordance with a doctor's prescription (see col. 1, lines 51-61).

With respect to Claim 11, Sarkozi teaches making an insert as previously described and teaches cutting the pads from larger pads (providing a sheet of the second insert material which is cut to fit into the area of reduced thickness in the first insert material) (see col. 6, lines 6-18). As Sarkozi is combined with Swartz, Swartz teaches contouring the laminate construction 20 (first insert) by pressing against the foot 24 (see fig. 3 and col. 6, lines 11-19) but does not appear to expressly teach vacuum forming the first insert material.

Brown teaches molding against a patient's foot by vacuum molding (see fig. 3 and col. 1, line 65 through col. 2, line 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Brown's vacuum molding technique in the process of Sarkozi as modified by Swartz pressing of the laminate in order to provide an better insert by preventing the formation of skin wrinkles across the critical area of the midtarsal joint and decompressing the soft tissue deformation (see Brown, col. 9, lines 16-21).

With respect to Claims 12 and 13, Sarkozi, as combined with Swartz and Healy, teaches making an insert as previously described. Sarkozi teaches making a customized insole liner by forming openings 15, 16, 17 through layers 12, 14 where support is needed (evaluating a patient's foot) (see fig. 3; col. 2, lines 26-30; col. 3, lines 22-27; and col. 3, line 64 through col. 4, line 6).

Sarkozi does not appear to expressly teach the steps of forming a mold of a lower portion of the patient's foot and forming a smooth cast of the lower portion of the patient's foot from the mold.

Brown teaches to product a negative mold of a foot to produce a positive form (forming a mold of a lower portion of the patient's foot and forming a smooth cast of the lower portion of the patient's foot from the mold) (see Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Brown's method of forming a negative and then positive mold with Sarkozi's method of making an insert in order to allow the insert to be made in accordance with a doctor's prescription (see col. 1, lines 51-61).

The steps' locations re necessarily met since the office is not distinguished from the laboratory in requirements of being differences of location or structure. Moreover, Brown teaches forming the insert upon the instruction of the doctor's prescription and mold, which would provide manufacturing in a manufacturing laboratory setting (wherein steps a, b, c, and i are performed in the office of a licensed professional practitioner and steps d, e, f, g, and h are performed in a laboratory for manufacturing custom fit inserts) (see col. 1, lines 16-23).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Butler whose telephone number is (571) 272-8517. The examiner can normally be reached on Mon.-Thu. 7:30 a.m.-5 p.m. and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/P. B./
Examiner, Art Unit 1791

/Monica A Huson/
Primary Examiner, Art Unit 1791